REMARKS/ARGUMENTS

1. Response to Notice of Non-Compliant Amendment

In accordance with the Notice of Non-Compliant Amendment, applicant has submitted herewith an amendment having a listing of claims that includes the text of all claims, including withdrawn claims.

Accordingly, applicant respectfully submits that the corrected amendment is in compliance with 37 CFR 1.121.

2. Response to Office Action

Each of the matters in the Office Action will be responded to under the corresponding subheading below.

a. Response to New Matter Objection

Applicant's previous amendment was objected to on grounds that the other phrases "administering to a patient on an ongoing basis" and "to stimulate and sustain production of cyclic AMP" constitute new matter. The specification was also objected to as failing to provide proper antecedent basis for the added phrases.

Applicant respectfully submits that support for the phrases is implicit in Applicant's disclosure and that the phrases consequently do not constitute new matter. Applicant's specification makes it clear that dosages are applied at daily rates that are continued over extended periods of time (e.g., at least 45-90 days in Example 2). It is therefore clear that this is a treatment that goes on for a period of time, and moreover that its purpose is to sustain the intended effect. The terms "ongoing basis" and "sustain" were selected as succinct expressions to this effect, and therefore do not constitute new matter.

In accordance with the Examiner's requirement, however, Applicant has hereby cancelled both phrases from the claims. Applicant has substituted the following phrase, which

distinguishes over the prior art for the reasons discussed below: "in accordance with a regimen that provides a predetermined daily dosage of said monoamine oxidase-A".

Express support for the added phrase is provided by Applicant's specification. For example, support for the term "regimen" appears at page 13, line 1, and support for "daily dosage" appears at page 12, line 33 and page 30, line 20.

Accordingly, it is respectfully submitted that the objection to new matter has been overcome by the present amendment.

b. Response to Rejection over Bykova

The Office Action maintained the rejection of claims 18 and 21-23 under 35 USC §102(b) as being anticipated by Bykova (SU '653). In support of the rejection, the Examiner discounted the limitation in Applicant's claims requiring treatment "on ongoing basis", on grounds that this lacked support in the specification. Furthermore, the Examiner held that "It is inherent that Bykova's method of administering monoamine oxidase-A or it's agonist would yield the production of histamine H_2 in an amount adequate to stimulate and sustain cyclic AMP at a level which would maintain myelin against undergoing self-degeneration. This is deduced because both [Applicant] and prior art discloses the same active step of monoamine oxidase-A administration."

Applicant respectfully submits that Bykova does not meet the requirements of Applicant's claims. To begin with, Applicant's claims are expressly directed to a method for therapeutic treatment of neurodegenerative conditions, whereas Bykova discloses a method for diagnosis, of MS (see Bykova, "*USE/ADVANTAGE*"). "Diagnosis" does not constitute "therapeutic treatment": In any ordinary sense, a "diagnosis" is a test or analysis to determine a condition or disease. It is not intended to have a healing, ameliorative or curative effect, as is a "therapeutic treatment". Moreover, although more than one diagnosis may be applied in some instances (e.g., to verify the accuracy of the results), a diagnosis is by definition a "one-time" event that is completed when the determination of the disease or condition has been made.

Bykova therefore does not show a method for therapeutic treatment, as is required by Applicant's claims. Moreover, Bykova does not show administering monoamine oxidase-A to

the patient "in accordance with a regimen that provides a predetermined daily dosage of said monoamine oxidase-A", which is also required by Applicant's claims. The reference is silent as to a regimen or daily dosages, this being consistent with the fact that the reference (as noted above) discloses a diagnosis and not a course of treatment.

Still further, Bykova does not show administering the compound "in an amount sufficient that said histamine H_2 is produced in an amount adequate to stimulate the production of cyclic AMP at a level which maintains myelin against undergoing self-degeneration", as is also required by Applicant's claims. In the Office Action, the Examiner asserted that this would be inherent in Bykova's method, "because both [Applicant] and the prior art discloses the same active step of monoamine oxidase-A administration"; however, Applicant respectfully disagrees: In order for a result to be "inherent" it must necessarily flow from the teachings of the reference (MPEP 2112). The mere fact that the compound (reserpine) is administered in Bykova does not mean that the compound is necessarily administered in an amount adequate that the myelin is maintained against self-degeneration, as is required by Applicant's claims: for example, in Bykova the amount may be insufficient to maintain the myelin. Consequently, it is not inherent in Bykova that the compound is administered in an adequate amount as required by Applicant's claims.

In order for a claim to be anticipated under 35 USC §102, the reference must teach every element of the claim (MPEP 2131). For the reasons explained above, Bykova fails to teach (a) a method for therapeutic treatment, (b) administering monoamine oxidase-A in accordance with a regimen that provides a predetermined daily dosage, or (c) administering the monoamine oxidase-A in an amount adequate to stimulate production of cyclic AMP at a level which maintains myelin against undergoing self-degeneration, each of which is required by Applicant's claims. Applicant therefore respectfully submits that Bykova fails to anticipate Applicant's claims and that the rejection under 35 USC §102 has been overcome.

c. Response to Rejection over Greenberg

The Examiner maintained the rejection of claims 18 and 21-23 under 35 USC §102(b) as being anticipated by Greenberg, for the reasons on record and for the reason that the "chronic

treatment" of rats taught by Greenberg constitutes a therapeutic treatment method. The reasons on record are that "it is inherent that said administration [of reserpine to rats] would increase the neuronal metabolism to histamine to a histamine agonist which stimulates production of c-AMP and increase neuronal metabolism of tele-methylhistamine to H_2 agonist" (Office Action dated 26 July 2002).

Applicant respectfully traverses the rejection. First, although Greenberg teaches "chronic treatment" of rats, it does not follow from this that Greenberg teaches a "therapeutic treatment". As noted above, a therapeutic treatment, as required by Applicant's claims, is to heal, ameliorate or cure a disease or condition. In Greenberg the reserpine is merely applied to the rats and the effect is observed with respect to beta-adrenergic receptor density, as compared with the effects of desmethylimipramine and trifluoperazine; from this, the reference merely concludes that the "theories of the mechanism faction of these compds. need reevaluation". In other words, the entire teaching of Greenberg is that the three compounds have different effects on receptor density and therefore must act through different mechanisms. Greenberg consequently does not teach a method for therapeutic treatment, as is required by Applicant's claims.

Furthermore, as noted above, Applicant's claims expressly require that the monoamine oxidase-A is administered "in an amount sufficient that said histamine H_2 agonist is produced in an amount adequate to stimulate production of cyclic AMP at a level which maintains myelin against undergoing self-degeneration." As noted above, the Examiner has previously asserted that this is inherent in Greenberg. Applicant respectfully disagrees: as was discussed in the preceding section, in order for a result to be inherent it must necessarily flow from the teachings of the reference. Similar to the case with Bykova, it does not necessarily follow from the mere fact that Greenberg administers reserpine that the compound is administered in an amount that is sufficient to maintain the myelin against self-degeneration; the amount may be insufficient or too great, and the reference is silent regarding myelin. It is therefore not inherent in Greenberg that the compound is administered in an adequate amount as required by Applicant's claims.

Finally, the reference does not teach the step of administering monoamine oxidase-A to a patient "in accordance with a regimen that provides a predetermined daily dosage", as is also required by Applicant's claims. The materials only say that the treatment is "chronic" and say nothing about a regimen or whether there were daily dosages.

In order to anticipate a claim, the reference must teach every element of the claim (MPEP 2131). For the reasons explained above, Greenberg fails to show (a) a method for therapeutic treatment, (b) administering monoamine oxidase-A in accordance with a regimen that provides a predetermined daily dosage, or (c) administering the compound in an amount sufficient to maintain myelin against undergoing self-degeneration. Applicant therefore respectfully submits that Greenberg fails to anticipate Applicant's claims, and that the rejection under 35 USC §102(b) is overcome.

d. Conclusion

Applicant respectfully requests reconsideration of the present application in view of the remarks set forth herein. It is believed that the claims are now in condition for allowance. If there is any matter that can be expedited by consultation with Applicant's attorney, such would be welcome. Applicant's attorney can normally be reached at the telephone number given below.

Signed at Bellingham, County of Whatcom, State of Washington this 24th day of July 2004.

Respectfully submitted,

ELAINE A. DELACK

By_____
Todd N. Hathaway, Reg. No. 32,991
119 N. Commercial St. #620
Bellingham, WA 98225-4437
(360) 647-1976